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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
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		10/509,075	09/22/2004
		First Named Inventor	
		Raoul Donath	
		Art Unit	Examiner
		3775	Woodall, Nicholas W.
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>35,340</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input checked="" type="checkbox"/> *Total of <u>2</u> forms are submitted.</p>			

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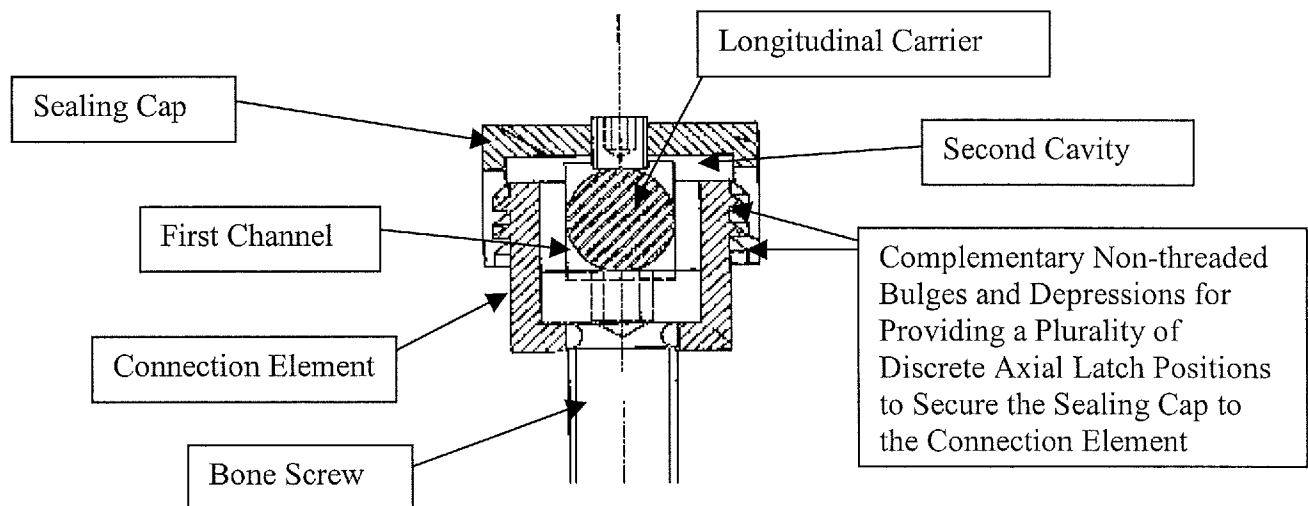
**APPLICANT'S REMARKS ACCOMPANYING
THE PRE-APPEAL BRIEF REQUEST FOR REVIEW**

In accordance with the *New Pre-Appeal Brief Conference Pilot Program*, Applicant hereby submits a Pre-Appeal Brief and a Pre-Appeal Brief Request for Review. The Pre-Appeal Brief and Pre-Appeal Brief Request for Review are being filed with a timely filed Notice of Appeal. Applicant respectfully submits that the claims have been twice rejected and are currently under Final Rejection, and, therefore, a Notice of Appeal is proper in accordance with 35 U.S.C. §134(a). Applicant respectfully requests detailed review of the rejections described herein, which Applicant respectfully submits are overcome by the below-listed arguments.

The Examiner rejected independent claim 1 under 35 U.S.C. §103(a) as being unpatentable over U.S.P.P.A.N. 2001/0012937 to Schaffler-Wachter ("Schaffler-Wachter") in view of U.S.P.N. 2,877,918 to Gardner ("Gardner") further in view of U.S.P.N. 5,989,254 to Katz ("Katz"). The Examiner also rejected claim 1 under §103(a) as being unpatentable over Schaffler-Wachter in view of Gardner further in view of U.S.P.N. 6,090,111 to Nichols ("Nichols"). The Examiner rejected independent claims 19 and 21 under §103(a) as being unpatentable over Schaffler-Wachter in view of Gardner.

Independent claims 1, 19 and 21 are directed to a device for connecting a longitudinal carrier to a bone screw and recite, *inter alia*, a connection element and a sealing cap. As representatively shown in the attached figure, the connection element includes an external surface and a first channel passing through the connection element for receiving a longitudinal carrier. The sealing cap includes a second cavity opening at a front end thereof for receiving the connection element, the second cavity including an internal surface. *The external surface of the connection element and the internal surface of the second cavity formed in the sealing cap include complementary non-threaded bulges and depressions for securing the sealing cap to the connection element, the bulges and depressions providing a plurality*

of discrete axial latch positions parallel to the central axis, each successive latch position axially displacing the sealing cap over the connection element...¹



Schaffler-Wachter discloses a pedicle screw assembly comprising a screw 1 and a cap 5, the cap 5 being formed by an inner part 6 and an outer part 7. The inner part 6 including a spherical cavity 24 for receiving the spherical head of the screw 1 and an upwardly cylindrical recess 14 for receiving a spinal rod 2. The outer part 7 is a U-shaped member having a downwardly facing partially spherical seat 16 for receiving the rod 2. The outer part 7 includes a pair of arms 9 having hooks 10 formed on an end thereof for engaging the under edges of the inner part 6.

As admitted by the Examiner, Schaffler-Wachter fails to disclose complementary non-threaded bulges and depressions for securing the sealing cap to the connection element, the bulges and depressions providing a plurality of discrete axial latch positions wherein each successive latch position axially displaces the sealing cap over the connection element. Rather, the Examiner relies upon Gardner for such disclosure.

¹ Independent claim 1 further recites, *inter alia*, a securing element. The examiner relies (i) upon Katz for disclosing the securing element wherein the securing element is a pin sized and configured to be pressed into a hole formed in the connection element, and (2) upon Nichols for disclosing the securing element wherein the securing element is a snap ring. Only for purposes of this Pre-Appeal Brief, the combination of Katz and/or Nichols for disclosure of a securing element is not challenged.

Referring to Figs. 1 and 2, Gardner is directed to a sealable bottle cap 10 that interacts with a bottle neck 12 formed on a bottle. The bottle cap 10 and bottle neck 12 are made from a distortable plastic material. The bottle cap 10 is moveable from a closed position (as shown in Fig. 2) to an open position (as shown in Fig. 1). In the closed position, the bottle cap 10 is sealed with respect to the bottle neck 12 so that fluid is prevented from leaking. In the open position, the bottle cap 10 is spaced from the bottle neck 12 so that fluid is permitted to escape from the cap 10. More specifically, the bottle cap 10 includes a single locking ring 16 for securing the cap 10 to the bottle 12 and two stop members 24, 26 for engaging a ring 14 formed on the bottle neck 12. Stop member 24 is located distally of stop member 26. In the closed position, stop member 26 engages the ring 14 such that the top of the bottle neck 12 is sealed by a skirt 30 so that any fluid contained in the bottle is prevented from leaking. In the open position, stop member 24 engages the ring 14 such that the top of the bottle cap 10 is spaced from the top of the bottle neck 12 so that fluid contained in the bottle can flow out of the cap 10. *The cap 10 is secured to the bottle 12 by a single locking ring 16. That is, in use, the stops 24, 26 do not secure the cap 10 to the bottle 12 but rather hold the cap 10 in the open position (ring 24) and in the closed position (ring 26).*

Applicant respectfully disagrees that one having ordinary skill in the art would modify the pedicle screw disclosed in Schaffler-Wachter in view of the bottle snap cap disclosed in Gardner to construct a device for connecting a longitudinal carrier to a bone screw wherein complementary non-threaded bulges and depressions are formed on a sealing cap and a connection element in order to connect the longitudinal carrier to the bone screw, as is claimed in the present application.

Gardner is directed to a sealable bottle cap 10 for coacting with a bottle neck 12 formed on a bottle container. The bottle cap 10 and bottle neck 12 being made from “a distortable plastic material, to the end that [the bottle cap 10] can be pressed onto the neck of the bottle.” *See* Gardner col. 2, lns. 37-

40. As such, **the disclosure of Gardner is unrelated to the field of medical devices and in particular is unrelated to spinal fixation devices.** “To rely on a reference under 35 U.S.C. 103, it must be analogous prior art.” *See* MPEP 2141.01(a). “[A] reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, *logically would have commended itself to an inventor's attention* in considering his or her invention as a whole.” *See KSR International co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007) (*emphasis added*). **Applicant respectfully submits that one having ordinary skill in the art of designing medical implants would not logically commend themselves to plastic, sealable bottle cap references, such as Gardner, when designing a device for connecting a longitudinal carrier to a bone screw.** Sealable bottle caps are so remote that they could not be considered reasonably pertinent and would not have logically commended themselves to Applicant's attention. MPEP 2141(a). Section I. Accordingly, Applicants respectfully submit that Gardner is not analogous prior art and may not be properly combined with the pedicle screw disclosed in Schaffler-Wachter.

Furthermore, even if one of ordinary skill in the art were to consider sealable bottle cap references, which Applicant refutes, Applicant respectfully submits that one of ordinary skill in the art would not consider Gardner because the problem being addressed by Gardner is not the same problem being addressed by Applicant. Gardner is directed to the design of a reusable, sealable bottle cap designed to satisfy several conditions. In particular, the bottle cap “must provide for the easy manual operation of the same; it must seal the contents of the bottle against leakage when in the closed position; and it must discharge only out of the discharge opening when it is in use.” *See* Gardner, col. 2, lns. 51-56. That is, Gardner was concerned with making a sealable cap to dispense liquids and wanted a cap that could remain secured to the bottle and move between an open position to dispense fluids and a closed position to retain the fluids.

In contrast, Applicant is concerned with designing an implant for spinal fixation, and specifically an implant for securing the position of a longitudinal carrier with respect to a bone screw in a patient's body. The sealing cap in the claimed invention is secured to the connection element in order to fix the position of the rod. The sealing cap must be able to withstand the forces in a spinal fixation procedure. The device is designed to minimize space requirements and to be implanted via a reduced number of surgical instruments and steps. The Applicant is not concerned with providing a sealable cap nor is the device in any way sealable as it contains various bores, channels, slots, openings, *etc.* for receiving and securing the position of the longitudinal carrier.

Furthermore, assuming *arguendo* that the Examiner's combination of Schaffler-Wachter and Gardner is proper, which Applicant refutes, the combination fails to disclose complementary non-threaded bulges and depressions for securing the sealing cap to the connection element. Similar to Schaffler-Wachter, Gardner discloses a single locking ring 16 for securing the cap 10 to the bottle 12. The stops 24, 26 in Gardner do not secure the cap 10 to the bottle 12 but rather hold the cap 10 in the open position (ring 24) and in the closed position (ring 26).

For all of the above reasons, Applicant respectfully submits that the combination of Gardner with Schaffler-Wachter is improper and the 35 U.S.C. 103 rejections should be withdrawn. Allowance of independent claims 1, 19 and 21 and dependent claims 2, 4, 5, 9, 10, 15-18 and 20 is respectfully requested.

Respectfully submitted,

Date: October 26, 2009

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